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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION	CIVIL NO. 3:10-CV-02033 (FLW) **JOHNSON & JOHNSON'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS OR, IN THE ALTERNATIVE, MOTION TO STAY** ORAL ARGUMENT REQUESTED

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Nominal defendant Johnson & Johnson ("J&J" or the "Company") respectfully submits this brief in support of its motion to dismiss, or in the alternative, motion to stay.

INTRODUCTION

Plaintiffs are shareholders in J&J, which is a global healthcare company headquartered in New Brunswick, New Jersey. This is a shareholder derivative action in which plaintiffs seek to bring a lawsuit on behalf of J&J against a number of current and former directors and officers of the Company. Plaintiffs have no individual injuries or causes of action. Instead, the Consolidated Amended Complaint (the "Complaint") alleges that J&J has been harmed by its directors and senior management and purports to assert legal claims that belong to J&J. The individual defendants include ten members of J&J's Board of Directors at the time this lawsuit was originally filed, and six current or former officers of the Company.

Plaintiffs broadly assert that, for more than a decade, defendants allegedly breached their fiduciary duties by "permitting and fostering a culture of systemic, calculated and widespread legal violations" across J&J's various business segments. (Cmplt. ¶ 3.) But plaintiffs have done nothing more than cherry pick specific issues arising at a handful of J&J's more than 250 subsidiaries, occurring at different points in time over the last 14 years, and then conclusorily allege that J&J's entire Board intentionally allowed illegal behavior to occur. The

Complaint's extreme rhetoric grossly distorts the record and ignores the fact that J&J's businesses operate in a highly-regulated environment. The Complaint also ignores the numerous remedial measures that J&J and its subsidiaries have taken in response to regulatory inquiries and product recalls.

As a threshold matter, the Complaint should be dismissed because it does not plead a proper derivative claim. Under New Jersey law, the duly elected directors – not individual shareholders – oversee the business and affairs of a corporation. This includes the power to bring and to maintain litigation on the corporation's behalf. Thus, the general rule is that shareholders may not bring a derivative lawsuit without first making a demand on the company's board of directors. When, as here, shareholders file a derivative suit without making a demand, a court may only allow the lawsuit to proceed if the shareholders make a particularized demonstration that demand would be futile.

To demonstrate that making a demand on J&J's Board would be futile, under Federal Rule of Civil Procedure 23.1 and applicable New Jersey law, plaintiffs must plead particular facts showing that a majority of J&J's Board acted in bad faith, knowingly violated the law, or received improper personal benefits. However, none of the directors in this case is alleged to have profited personally from the alleged breaches of fiduciary duty. Nor have plaintiffs pleaded *with*

particularity that the distinguished businesspeople, scientists, and academics comprising J&J's Board acted in bad faith or knowingly violated the law.

Plaintiffs have not pleaded any particularized facts showing that the Board knew of the alleged misconduct at J&J's subsidiaries and intentionally did nothing to prevent or stop it. Plaintiffs' allegations against the Board are not only purely conclusory, they are wholly implausible. The allegation that J&J's Board would *intentionally* put the well-being of consumers and patients at risk is absurd. Accordingly, these plaintiffs were not excused from making a demand upon the Board, and the Complaint should be dismissed.

Alternatively, the Court should stay this action. Although the plaintiffs in this case did not make a demand on J&J's Board, numerous other shareholders did so. They sent letters to the Board demanding that the Board investigate whether there has been any actionable wrongdoing. The subject matter of those various demand letters overlaps with essentially all of the matters alleged in the Complaint. As this Court already has been apprised, J&J's Board appointed a Special Committee consisting of four independent Board members to review and investigate the assertions made in those demand letters, as well as the allegations made in plaintiffs' Complaint. That investigation is well underway. Under the circumstances, the Court should alternatively stay this case pending the Special

Committee's investigation and recommendations regarding what actions, if any, J&J should take.

FACTUAL BACKGROUND

J&J is a global healthcare company incorporated in New Jersey. (Cmplt. ¶ 28.) J&J is a holding company, with more than 250 subsidiaries conducting business in virtually every country of the world. J&J and its subsidiaries have approximately 115,500 employees worldwide engaged in the research, development, manufacture, and sale of a broad range of healthcare products. The Company currently has three primary lines of business: (1) consumer healthcare products; (2) pharmaceutical drugs; and (3) medical devices and diagnostics.

J&J is a large, diverse, and successful enterprise. Since 1997, J&J's sales have grown from $22.6 billion to $61.6 billion. (*Compare* 1997 Form 10-K, at 3 *with* Form 8-K, filed January 25, 2011 (J&J's public filings are available at www.investor.jnj. com/governance/sec-filings.cfm).) Shareholders have benefited. Net earnings per share have increased from $2.47 per share in 1997 to $4.76 per share in 2010. (*Compare* 1997 Form 10-K, at 3 *with* Form 8-K, filed January 25, 2011.)

As of the date the original complaint in this case was filed, J&J's Board was comprised of the following eleven highly-accomplished individuals:

- **Mary Sue Coleman, Ph.D.** has been a director since 2003. (Cmplt. ¶ 29.) She has served as President of the University of Michigan since August 2002 and is a professor of biological chemistry in the University of Michigan Medical School and a professor of chemistry in the University of Michigan College of Literature, Science, and the Arts.
- **James Cullen** has been a director since 1995. (*Id.* ¶ 30.) He was the President and COO of Bell Atlantic Corporation until 2002 and he is a director of the Eisenhower Medical Center.
- **Michael Johns, M.D.** has been a director since 2005. (*Id.* ¶ 31.) He has served as Chancellor of Emory University since October 2007. From 1996 to 2007, Dr. Johns served as Executive Vice President for Health Affairs and CEO of the Robert W. Woodruff Health Sciences Center of Emory University. From 1996 to 2007, he served as the Chairman of the Board of Emory Healthcare, the largest health care system in Georgia. From 1990 to 1996, Dr. Johns served as Dean of the Johns Hopkins School of Medicine and Vice President of the Medical Faculty at Johns Hopkins University.
- **Arnold Langbo** had been a director since 1991 and retired from the Board effective with the Company's annual meeting on April 22, 2010. (*Id.* ¶ 32.) He previously was COO and Chairman of the Board of the Kellogg Company, and a member of the board of directors of the Hershey Company and Whirlpool Corporation.
- **Susan Lindquist, Ph.D.** has been a director since 2004. (*Id.* ¶ 33.) She is a member of the Whitehead Institute, a non-profit, independent research and educational institution; a Professor of Biology at the Massachusetts Institute of Technology; and an investigator for the Howard Hughes Medical Institute.
- **Leo Mullin** has been a director since 1999. (*Id.* ¶ 34.) Mr. Mullin was CEO of Delta Air Lines, Inc. until December 2003 and Chairman of Delta's Board until April 2004. Mr. Mullin is a member of both The Business Council and the Advisory Board of the Carter Center. He also is Chairman of the Board of the Juvenile Diabetes Research Foundation.
- **William Perez** has been a director since 2007. (*Id.* ¶ 35.) Mr. Perez served as President and CEO of the Wm. Wrigley Jr. Company from

2006 to 2008. Before joining Wrigley, Mr. Perez served as President and CEO of Nike, Inc. Previously, he spent 34 years with S.C. Johnson & Son, Inc., including eight years as its President and CEO.

- **Charles Prince** has been a director since 2006. (*Id.* ¶ 36.) Mr. Prince is Chairman of Sconset Group, LLC and a Senior Counselor for Albright Capital Management LLC, a Washington, D.C. based investment firm. Mr. Prince served as CEO of Citigroup Inc. from 2003 to 2007 and as Chairman of Citigroup's Board from 2006 to 2007.
- **David Satcher, M.D., Ph.D.** has been a director since 2002. (*Id.* ¶ 37.) Mr. Satcher was Surgeon General of the United States from 1998 to 2002. He served as the U.S. Assistant Secretary for Health from 1998 to 2001. He is now a director of the Center of Excellence on Health Disparities and a director of the Satcher Health Leadership Institute. He also is the Poussaint-Satcher-Cosby Chair in Mental Health at the Morehouse School of Medicine.
- **Anne Mulcahy** has been a director since 2009. Ms. Mulcahy retired as Chairman of the Board of Xerox Corporation in May 2010 and CEO of Xerox Corporation in July 2009. She also is on the board of directors of Citigroup Inc. and The Washington Post Company.
- **William Weldon** has been a director since 2001. He is the Company's Chairman and CEO. He has extensive experience in the healthcare field, including serving as Worldwide Chairman of the Pharmaceuticals Group. (*See id.* ¶ 38.)

Plaintiffs do not make any allegations of wrongdoing against director Mulcahy.

Plaintiffs nonetheless claim that the other ten directors breached their fiduciary duties to the Company.[1]

[1] Plaintiffs also seek to bring claims on behalf of J&J against six additional current or former officers: Russell Deyo, Alex Gorsky, Peter Luther, Christine Poon, Joseph Scodari, and Nicholas Valeriani. (Cmplt. ¶¶ 39-46.) However, because these individuals were officers of the Company, and not Board members at the time the initial suit was filed, they are not relevant to the analysis of whether demand upon the Board was required.

PLAINTIFFS' ALLEGATIONS

Plaintiffs broadly allege that the above ten J&J directors, all of whom hold, or have held, prominent positions in the healthcare field and/or in this country's largest corporations, permitted J&J's subsidiaries to systematically violate the law. (*Id*. ¶ 3.) Plaintiffs base their allegations on certain recalls, investigations, and lawsuits involving eight different J&J subsidiaries at different points of time between 1997 and 2010. Briefly summarized, plaintiffs' allegations consist of the following:

Product Recall Allegations. Plaintiffs allege that federal regulations were violated, prompting four sets of product recalls at three J&J subsidiaries. First, plaintiffs claim that McNeil Consumer Healthcare ("McNeil") improperly retrieved certain packages of Motrin in a so-called "phantom recall." (*Id*. ¶¶ 95-102.) Second, plaintiffs assert that violations of Good Manufacturing Practices at McNeil's Las Piedras plant delayed the discovery that chemically-treated wood pallets were causing unforeseen odors, thereby exacerbating eventual product recalls. (*Id*. ¶¶ 103-12.) Third, plaintiffs allege that violations of Good Manufacturing Practices at McNeil's Fort Washington plant caused other product recalls. (*Id*. ¶¶ 113-25.) Fourth, plaintiffs allege that subsidiary Vision Care Inc. conducted a recall of Acuvue contact lenses and that subsidiary DePuy Orthopaedics had to recall certain hip replacement devices. (*Id*. ¶¶ 126-41.)

Off-Label Marketing Allegations. Plaintiffs allege that three J&J subsidiaries improperly marketed certain pharmaceutical drugs or products for uses not approved by the FDA. To put these allegations in context, however, some background is essential. The FDA approves pharmaceutical drugs and products for particular uses. Physicians, however, are free to (and do) prescribe drugs or products that they think are appropriate to treat medical conditions, including off-label uses. *See* 21 U.S.C. § 396; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 & n.5 (2001). Physicians may ask healthcare companies for information regarding off-label uses to ensure that they are prescribing them safely, and the companies may provide that information. *See, e.g.*, 21 C.F.R. §§ 99.1, 99.101; *Hologic, Inc. v. SenoRx, Inc.*, 2008 WL 1860035, at *18 (N.D. Cal. Apr. 25, 2008).

In short, off-label use of pharmaceutical products and drugs is common throughout the medical profession. Indeed, federal and state governments are well aware of and contribute to off-label use: if a physician prescribes a drug for a medically-necessary off-label use, federal and state Medicare and Medicaid programs will reimburse the cost of the drug. *See* 42 U.S.C. §§ 1395y(a)(1)(a), 1396r-8. Thus, that a company has off-label sales or provides physicians with information about off-label uses of drugs or products is neither illegal nor

improper. The restriction is only that the company not market the drugs or products for off-label uses.

Here, plaintiffs allege that four J&J subsidiaries improperly marketed their drugs and products for off-label uses. First, plaintiffs allege that starting in approximately 1997, Janssen Pharmaceutica, Inc. ("Janssen") (now part of Ortho-McNeil Janssen Pharmaceuticals, Inc. ("OMJPI")) marketed its antipsychotic drug Risperdal for off-label uses. (Cmplt. ¶¶ 168-92.) Second, plaintiffs allege that starting in 2001, J&J subsidiary Ortho-McNeil Pharmaceutical, Inc. (also now part of OMJPI) marketed its anti-epilepsy drug Topamax for off-label uses. (*Id.* ¶¶ 193-208.) Third, plaintiffs allege that starting in 2003, J&J subsidiary Scios, Inc. marketed its drug Natrecor, which is used by patients with congestive heart failure, for off-label uses. (*Id*. ¶¶ 209-40.) Fourth, plaintiffs allege that J&J subsidiary Cordis Corp. marketed its biliary stents for off-label uses. (*Id*. ¶¶ 241-53.)

Omnicare Allegations. Plaintiffs next allege that from 1999–2004, two of J&J's subsidiaries – Janssen and Johnson & Johnson Health Care Systems, Inc. ("JJHCS") – paid kickbacks to Omnicare, Inc. in exchange for Omnicare's pharmacists recommending Janssen's drugs to its nursing home patients. (*Id*. ¶¶ 255-72.)

DePuy Allegations. Plaintiffs finally allege that from 2002–2006, subsidiary DePuy Orthopaedics paid inducements to surgeons to use DePuy hip and knee replacement and reconstructive products in their surgeries. (*Id.* ¶¶ 273-77.)

PROCEDURAL BACKGROUND

Co-lead plaintiff Jeanne M. Calamore filed her derivative complaint with this Court on April 21, 2010. In the next several months, other shareholders filed five additional derivative complaints. None of these shareholders made a demand on J&J's Board prior to filing suit.

On August 17, 2010, the Court consolidated the six derivative cases into one action: *In re Johnson & Johnson Derivative Litigation*, Case No. 10-cv-2033, and appointed co-lead plaintiffs and co-lead counsel. On December 17, 2010, plaintiffs filed the Complaint that is the subject of this motion. The Complaint asserts that plaintiffs did not make a demand because, according to plaintiffs, demand would be futile.

Although plaintiffs did not make the required demand, since February 2010, nine other shareholders have made demands upon J&J's Board with respect to some or all of the same matters alleged in the Complaint. (*See* Decl. of D. Eakeley ¶¶ 3-5.) In response to the demand letters, the Board appointed a Special Committee to review and investigate the shareholders' assertions, as well as the allegations made in this derivative litigation. (*Id.*) The Special Committee is

comprised of the four independent directors who had most recently joined the Board at the time the Committee was formed: Michael Johns, Anne Mulcahy, William Perez, and Charles Prince. (*Id*. ¶ 3.)

The Special Committee has retained independent legal counsel, Lowenstein Sandler P.C., to assist the Committee with its investigation. (*Id*. ¶ 4.) The investigation is well underway; 22 interviews have been conducted and more than one million pages of documents have been collected and reviewed. (*Id*. ¶ 6.) Once it completes its investigation, the Special Committee will recommend to the Board what actions, if any, should be taken. (*Id*. ¶ 3.)

ARGUMENT

This shareholder derivative action should be dismissed. Plaintiffs did not make the required demand on J&J's Board and have not demonstrated that demand is excused, as required by Federal Rule of Civil Procedure 23.1 and New Jersey law. *See In re PSE&G S'holder Litig.*, 173 N.J. 258, 278-79 (2002); Fed. R. Civ. P. 23.1. Plaintiffs allege that demand should be excused based on a list of various regulatory investigations, litigation, and recalls involving eight of J&J's more than 250 subsidiaries at different points over the past fourteen years. But plaintiffs' cherry-picked list of issues does not provide any basis on which to excuse demand. As is true for all companies in the healthcare/pharmaceutical industry, J&J is subject to regulatory inquiry and is expected to, and does, communicate frequently

with the FDA regarding the promotion and manufacture of its products. (*See, e.g.*, Cmplt. ¶ 54.) That J&J has received letters from the FDA with respect to certain of its practices and has promptly responded to those letters is precisely the way the healthcare industry operates. Likewise, that J&J has been subject to litigation or regulatory investigation is typical for companies in the closely-regulated healthcare industry.

Moreover, and most importantly, plaintiffs have not pointed to *any* particularized fact showing that the J&J directors (the only individuals relevant to the demand futility analysis) ignored red flags and intentionally allowed wrongdoing to occur at J&J's subsidiaries. The fact that a healthcare company has been subject to litigation or regulatory inquiry does not mean that the directors acted in bad faith or knowingly allowed wrongdoing. Indeed, as discussed in detail below, numerous courts have rejected the very kind of conclusory allegations plaintiffs make here regarding the J&J Board's oversight of off-label marketing and compliance with FDA regulations. *See, e.g., In re Merck & Co., Inc. Sec., Deriv., & ERISA Litig.*, 2008 WL 2788400, at *7 (D.N.J. June 17, 2008) (dismissing derivative complaint and denying leave to amend: plaintiffs' allegations that directors allowed improper marketing of Merck's blockbuster drug Vioxx did not excuse demand under New Jersey law because plaintiff failed to "plead particularized facts regarding the [d]irectors' participation in the alleged

wrongdoing, that is, exactly how they were involved in the failure to halt or decrease the promotion and sale of Vioxx"); *Markewich v. Collins* (hereinafter "*Medtronic Deriv. Litig.*"), 622 F. Supp. 2d 802 (D. Minn. 2009) (dismissing derivative complaint: plaintiffs' allegations that board knew of off-label marketing and systemic legal violations based on recalls, *qui tam* litigation, and prior settlements were too conclusory to excuse demand); *King v. Baldino*, 2010 WL 5078008 (3d Cir. Dec. 14, 2010) (affirming dismissal of derivative complaint: plaintiffs did not allege any red flags showing that directors knew about and allowed off-label marketing to occur); *Bronstein v. Austin*, 2008 WL 4735230 (N.D. Ill. May 30, 2008) (dismissing derivative complaint: plaintiffs' allegation that directors should have known about violations of FDA manufacturing regulations by virtue of their positions on board committees was insufficient to excuse demand). It is not enough for plaintiffs to claim with the benefit of hindsight that the directors should have made different decisions. Plaintiffs must make particularized allegations that the J&J Board knowingly violated the law at the time the alleged misconduct occurred. Plaintiffs' Complaint falls far short. Accordingly, demand is not excused and the Complaint should be dismissed.

In the alternative, if this Court does not dismiss this case, the Court should stay the case pending the review and investigation of the Special Committee into,

inter alia, the matters alleged in the Complaint. As discussed below, there is no reason for this case to proceed at this time.

I. THE COMPLAINT SHOULD BE DISMISSED BECAUSE PLAINTIFFS' ALLEGATIONS DO NOT EXCUSE PLAINTIFFS' FAILURE TO MAKE A DEMAND.

J&J is incorporated under New Jersey law (Cmplt. ¶ 28), and New Jersey law governs whether plaintiffs may maintain this shareholder derivative action. *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 108-09 (1991). Under New Jersey law, the business and affairs of a corporation are managed under the direction of its board of directors. N.J.S.A. 14A:6-1. New Jersey law provides a "powerful presumption" that directors perform their duties to the corporation in accordance with the business judgment rule, *i.e.*, on an informed basis, in good faith, and in the honest belief that the action taken was in the best interests of the company. *In re Merck & Co., Inc. Sec., Deriv., & ERISA Litig.*, 493 F.3d 393, 402 (3d Cir. 2007). One of the most significant responsibilities that rests with the directors of a corporation is "[t]he decision to bring a lawsuit or to refrain from litigating a claim on behalf of the corporation." *Id*. at 399.

Because a shareholder derivative action, in which a shareholder seeks to pursue a claim on a corporation's behalf, necessarily intrudes upon the powers ordinarily vested in the directors, a shareholder's ability to bring a derivative action is carefully limited by the demand requirement. That is, a shareholder must, before

filing suit, make a demand on the board to obtain the action the shareholder desires. *PSE&G*, 173 N.J. at 277-82; Fed. R. Civ. P. 23.1.[2]

The demand requirement is not a technicality. "In light of how shareholder derivative actions may usurp director control, courts have warned of the pitfalls of unchecked shareholder derivative litigation." *In re Merck & Co., Inc. Deriv. & ERISA Litig.*, 2006 WL 1228595, at *4 (D.N.J. May 5, 2006), *remanded on other grounds*, 493 F.3d 393 (3d Cir. 2007). "[A]lthough [derivative] litigation may compensate the corporation for injuries sustained as a result of wrongful conduct, it also may have a negative effect on corporate governance when frivolous lawsuits initiated by opportunistic shareholders are brought . . . [and] [i]f abused, . . . can impede the best interests of the corporation." *PSE&G*, 173 N.J. at 278.

There are thus only "narrow exceptions when shareholders will be excused from making demand." *Merck*, 493 F.3d at 399. If a shareholder plaintiff fails to make the required demand, it may bring a claim on the corporation's behalf only if the complaint pleads *with particularity* why demand on the board would have been

[2] In this derivative action, demand is both a pleading and a substantive prerequisite. Federal Rule of Civil Procedure 23.1 requires that a complaint in a derivative action allege with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action or for not making the effort. Whether the complaint sufficiently pleads that demand would have been futile is a question of state substantive law, which is governed by the state of incorporation of the corporate defendant, in this case New Jersey. *Kamen*, 500 U.S. at 108-09; *PSE&G*, 173 N.J. at 277-82.

futile. *PSE&G*, 173 N.J. at 282; Fed. R. Civ. P. 23.1. The requirement that a derivative plaintiff plead demand futility "with particularity" was adopted "to halt abuses" by ensuring that shareholders would use the courts only as "a last resort." *In re Prudential Ins. Co. Deriv. Litig.*, 282 N.J. Super. 256, 270 (Ch. Div. 1995).

A. Plaintiffs' Complaint Must Plead With Particularity That A Majority Of The Directors Are Interested.

In its seminal *PSE&G* decision, the New Jersey Supreme Court adopted the standards set forth under Delaware law for pleading demand futility. *See PSE&G*, 173 N.J. at 279-82. With respect to a derivative suit, like the one here, that purports to challenge a board's alleged failure to exercise effective oversight of a subsidiary, or alleged failure to prevent or stop misconduct, the New Jersey Supreme Court adopted the ruling in *Rales v. Blasband*, 634 A.2d 927, 933 (Del. 1993). *PSE&G*, 173 N.J. at 281-82 (holding that the *Rales* test applies to allegations that directors failed to act); *see also Fagin v. Gilmartin*, 432 F.3d 276, 282-83 (3d Cir. 2005) (applying *Rales* test to allegations that board did not prevent or correct misconduct at subsidiary companies); *Richardson v. Ulsh*, 2007 WL 2713050, at *10 (D.N.J. Sept. 13, 2007) (applying *Rales* test to allegations that directors failed to act "despite obvious red flags").

Under New Jersey's application of the *Rales* standard, demand futility is established only if the complaint pleads particularized facts establishing "a

reasonable doubt that, as of the time the complaint [was] filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." *Rales*, 634 A.2d at 934. The original complaint in this case was filed on April 21, 2010. At that time, J&J's Board was comprised of eleven directors, ten of whom were outside directors. Thus, plaintiffs can demonstrate demand futility only by pleading with particularity that six of J&J's directors were not independent or disinterested, and thus would not have been able to exercise business judgment in responding to shareholders' demands.[3]

Directors are presumed to be disinterested and independent. *Prudential*, 282 N.J. Super. at 278. A director's independence is determined by whether the "director's decision is based on the corporate merits of the subject before the board

[3] The requirement that demand futility be evaluated as of the time the original complaint was filed – *i.e.*, the time a demand should have been made – is significant for two reasons. First, demand futility is evaluated against the composition of the Board on the date the first of the consolidated suits was filed. *See Merck*, 2008 WL 2788400, at *7 n.7; *Merck*, 2006 WL 1228595, at *8 (treating commencement of the consolidated case as "the date the first shareholder derivative action . . . was filed"). Second, events occurring after the earliest derivative suit was commenced may not be used to establish demand futility. *See Merck*, 493 F.3d at 400-01; *In re Intel Corp. Deriv. Litig.*, 621 F. Supp. 2d 165, 175-76 & n.3 (D. Del. 2009); 3 Stephen A. Radin, *The Business Judgment Rule: Fid. Duties of Corp. Directors* 3969–76 (Aspen 6th ed. 2009) ("Events that have not occurred at the time shareholders seek to wrest control of a corporate claim away from a corporation's board of directors cannot provide the basis for the evaluation concerning director disinterestedness and independence that plaintiffs must make *at the time* they seek to seize the claim.") (collecting cases).

rather than extraneous consideration[s] or influences." *PSE&G*, 173 N.J. at 290. A director is considered interested if "divided loyalties are present, or where the director stands to receive a personal financial gain . . . not equally shared by the shareholders." *Id.* at 289-90.

Plaintiffs do not contend that any of the ten outside directors are not independent. Plaintiffs also do not contend that any director received any financial or other benefit from the alleged misconduct. Unlike cases where a director allegedly engaged in self-dealing or insider trading, none of the directors in this case is alleged to have profited personally from the alleged breaches of fiduciary duty. The directors are thus not interested on that basis.

Instead, plaintiffs' overarching excuse for not making the required demand is the claim that a majority of the directors purportedly breached their fiduciary duties by permitting various J&J subsidiaries to engage in allegedly improper conduct. (Cmplt. ¶¶ 286-89.) Plaintiffs then assert that because they have accused the directors of breaching their fiduciary duties, demand on the Board would be futile because the directors face a substantial risk of liability and are thus interested. (*Id.* ¶¶ 286-96.) Plaintiffs are wrong.

Pleading demand futility based on the risk of potential personal liability is a very difficult standard for a derivative plaintiff to meet. *Merck*, 493 F.3d at 402. Indeed, a claim, like the one plaintiffs make here, alleging that a director's failure

to exercise oversight has subjected him to personal liability, has been stated by the Delaware Chancery Court to be "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996). Conclusory allegations that the directors participated in or approved of the challenged conduct are not sufficient. *PSE&G*, 173 N.J. at 290. Likewise, allegations that directors would be required to sue themselves are not enough. *Id.*; *Kanter v. Barella*, 489 F.3d 170, 180 (3d Cir. 2007) ("A plaintiff may not bootstrap allegations of futility merely by alleging that the directors participated in the challenged transaction or that they would be reluctant to sue themselves.") (quoting *Prudential*, 282 N.J. Super. at 276). Rather, demand futility can be established only in those "rare cases" when the plaintiff pleads with particularity that the board has engaged in "egregious" behavior subjecting the directors to a "substantial" risk of liability. *Merck*, 2008 WL 2788400, at *5; *see also Fagin*, 432 F.3d at 283 (a "mere threat" of personal liability is not enough to establish demand futility). "The allegations must not simply demonstrate an aloof or negligent Board, but nonfeasance that rose to the level of egregiousness or bad faith." *Merck*, 493 F.3d at 404; *see also Stone v. Ritter*, 911 A.2d 362, 369-70 (Del. 2006) (requiring showing of bad faith).

B. Plaintiffs' Complaint Also Must Plead With Particularity That A Majority Of The Directors Knowingly Acted Against The Interests Of The Company Or Knowingly Violated The Law.

Moreover, J&J's Certificate of Incorporation contains an express provision that exempts J&J's directors from liability to the full extent of New Jersey law. (*See* Restated Certificate of Incorporation, attached as Ex. 1 to Certification of Donald Robinson, at ¶ Ninth (exculpation provision).[4]) Where, as here, directors are protected by such a charter provision, plaintiffs' pleading burden is even higher. *Kanter v. Barella*, 388 F. Supp. 2d 474, 479 n.9 (D.N.J. 2005) ("Plaintiff's effort to demonstrate a substantial likelihood of liability is also stifled by the exculpation provision contained in [the company's] Certificate of Incorporation."), *aff'd*, 489 F.3d 170 (3d Cir. 2007); *Merck*, 2006 WL 1228595, at *14 ("Plaintiffs' ability to demonstrate a directorial interest based upon a substantial likelihood of personal liability is also undermined by the exculpatory provision contained in [the company's] corporate charter."). When directors are protected by an exculpation clause, a substantial threat of liability may be found to exist only if the plaintiff pleads a *non-exculpated* claim against the directors based on particularized facts. *See Kanter*, 388 F. Supp. 2d at 479 n.9; *Merck*, 2006 WL 1228595, at *14. By virtue of the terms of J&J's Certificate of Incorporation, under New Jersey law,

[4] The Court may take judicial notice of J&J's Certificate of Incorporation. *See Merck*, 2006 WL 1228595, at *14 n.6.

J&J's directors are not liable for a breach of the duty of care. N.J.S.A. 14A:2-7(3). They can be liable *only* for claims arising out of a breach of a "duty of loyalty" (which requires that the directors knew or believed that they were not acting in the best interests of the corporation in connection with a matter in which they had a material conflict of interest), a "knowing violation of the law," or conduct "resulting in receipt by such person of an improper personal benefit." *Id*.

Thus, to establish that the directors are not able to consider a demand in this case, plaintiffs must demonstrate that the directors knew about the alleged misconduct, knew it was illegal, and egregiously declined to stop or prevent it. *See Merck*, 2008 WL 2788400, at *5-6; *Merck*, 2006 WL 1228595, at *14-15. The Complaint comes nowhere close to pleading such allegations.

Instead, plaintiffs offer three sets of non-particularized allegations in their attempt to excuse demand: (1) the Board allegedly received red flags and thus must have known about the alleged misconduct but nonetheless did nothing to stop it (Cmplt. ¶¶ 278-85, 292); (2) the alleged misconduct by J&J's various subsidiaries is so "systemic, widespread, and sustained" that the Board must have condoned it (*id.* at Heading G, ¶¶ 286-93); and (3) the Board members served on various Board committees, whose responsibilities included overseeing legal and regulatory compliance (*id*. ¶¶ 297-300). For the reasons below, these allegations, whether considered individually or collectively, do not excuse demand.

C. The Complaint's Alleged Red Flags Do Not Establish A Substantial Likelihood Of Liability.

Plaintiffs allege that the director defendants face a substantial likelihood of liability for the Product Recall, Off-Label Marketing, Omnicare, and DePuy Allegations because they intentionally ignored so-called red flags that such conduct was occurring at J&J's subsidiaries. To establish a substantial likelihood of liability on such a theory, the Complaint must allege particularized facts showing that: the Board knew of the alleged red flag; the Board learned from the red flag that misconduct was occurring; and the Board acted "egregiously" in failing to correct the misconduct. *See, e.g.*, *Merck*, 493 F.3d at 402-04; *Kanter*, 388 F. Supp. 2d at 479-81 & n.9; *see also In re Intel Corp. Deriv. Litig.*, 621 F. Supp. 2d 165, 171, 174-75 (D. Del. 2009). The Complaint fails to meet this stringent standard. There are no particularized allegations that the Board knew of any red flags in advance of the alleged misconduct, let alone particularized allegations that the Board egregiously failed to take action in response to the purported red flags.

1. The Product Recall Allegations Do Not Show That The Board Knowingly Acted Against The Interests Of The Company Or Knowingly Violated The Law.

Plaintiffs allege that the Board faces a substantial likelihood of liability with respect to four sets of product recall allegations: (1) the 2009 "phantom recall";

(2) the 2009 and 2010 recalls of McNeil products manufactured at Las Piedras; (3) the 2009 and 2010 recalls of McNeil products manufactured at Fort Washington; and (4) the 2010 recalls of Acuvue and DePuy products. Plaintiffs fail, however, to establish that the directors knowingly acted against the interests of the Company or knowingly violated the law, and thus plaintiffs fail to establish a substantial likelihood of Board liability for any of these allegations.

a. The 2009 "Phantom Recall"

The Complaint alleges that the Board faces a substantial risk of personal liability for the purported "phantom recall" of Motrin products. In mid-2009, McNeil hired a contractor to retrieve a small amount of unsold packages of one type of Motrin from certain retailers. (Sept. 30, 2010 Testimony of W. Weldon before the House Committee on Oversight & Government Reform at 3-4 (cited in Cmplt. ¶¶ 162-63), attached as Ex. 2 to Robinson Cert.)[5] The FDA was apprised of McNeil's actions and agreed that, because of this particular product's limited distribution and the absence of any health risk, the retrieval should be classified as a market withdrawal rather than a recall. (*See id*.) McNeil subsequently, in

[5] The Court may take judicial notice of the sources cited in this brief because they are "matters of public record, documents integral to or explicitly relied upon in the complaint and documents incorporated into the complaint by reference." *Merck*, 2008 WL 2788400, at *4; *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

consultation with the FDA in the summer of 2009, upgraded the retrieval and issued a formal recall. (*See id.*)[6]

The Complaint's allegations concerning this event are pure rhetoric and are devoid of any particularized pleading establishing a substantial likelihood of Board liability. Not only did McNeil advise the FDA of the retrieval, but plaintiffs allege no red flags that should have alerted the J&J Board in 2009 to any alleged unlawful conduct at McNeil in connection with these events. Likewise, plaintiffs do not plead any particularized facts suggesting that the J&J Board even knew of the recall in advance, let alone that it declined to prevent illegal conduct.

b. The 2009 and 2010 Las Piedras Recalls

Plaintiffs claim that the Board faces a substantial risk of liability for the recalls of products manufactured at McNeil's Las Piedras facility. In late 2009,

[6] The Complaint's allegations regarding this event are false on their face. The June 2009 memorandum plaintiffs repeatedly cite in the Complaint (*see, e.g.*, Cmplt. ¶ 96), was not written by McNeil, but rather by the contractor hired to execute the retrieval. The Complaint asserts that the recall was a red flag "in the second half of 2008," but the retrieval took place in 2009. Moreover, there has been no finding by the House Committee on Oversight and Government Reform of any "pattern of concealment" by McNeil, much less by J&J. The quotation included in paragraphs 6 and 102 of the Complaint is a personal statement made by a single Congressperson during the September 30, 2010 Committee hearing. Plaintiffs deliberately omit to cite that another Congressperson expressly stated, in connection with that same hearing, that the FDA had been kept apprised of McNeil's efforts to effect the product retrieval. (*See* Sept. 28, 2010 letter from Rep. Issa to DHHS Inspector General (requesting an investigation into the FDA's "apparent[] attempt[s] to mislead Congress" regarding the "phantom recall"), attached as Ex. 3 to Robinson Cert.)

McNeil determined that chemically-treated wood pallets used by suppliers to the Las Piedras facility had contaminated products with the chemical 2-4-6-tribromoanisole ("TBA"). (J&J Jan. 15, 2010 Press Release (available at http://www.fda.gov/safety/recalls/ucm197746.htm).) TBA gives off a musty or moldy odor, though it causes no known significant adverse health effects. (*Id*.) Upon making this determination, McNeil commenced a recall of the affected products in November 2009. (*See id*.)

In January 2010, the FDA completed its inspection of the Las Piedras facility. As a result of that inspection, the FDA issued a Form 483 inspection report on January 8, 2010, and sent a Warning Letter to McNeil on January 15, 2010. On January 15, 2010, McNeil promptly announced a broader TBA-related recall of products manufactured at Las Piedras. (*See id*.)

The Complaint does not establish any possibility of the J&J Board's liability with respect to these events. First, plaintiffs do not allege any red flags that should have alerted the Board to a problem at Las Piedras in advance of the November 2009 recall. (*See* Cmplt. ¶¶ 282–83, 285.)[7] Moreover, there are no allegations that

[7] The Complaint alleges that a "2008 FDA report outlines an increasing number[s] of complaints about consumer tablets of Tylenol Arthritis." (Cmplt. ¶ 92.) Plaintiffs did not attach a copy of the alleged report to the Complaint and J&J's extensive investigation has not revealed any such report. Rather, it appears that Paragraph 92's allegations are based on the January 8, 2010, Las Piedras Form 483

McNeil failed to promptly attempt to correct any manufacturing issues. To the contrary, the recalls were responses to McNeil's determination of the source of the problem. (*See id.*; FDA, *Enforcement Report for Jan. 6, 2010* (available at http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm196398.htm) (listing these recalls as voluntary and firm-initiated).) McNeil also responded to the FDA's January 15, 2010, Warning Letter within the time allotted and McNeil executives promptly met with the FDA on February 19, 2010 (Cmplt. ¶ 110). In addition, McNeil announced that it was banning the use of the chemically-treated wood pallets that caused the contamination and requiring all of its suppliers to abandon them as well, thereby preventing future TBA contamination. (*See* J&J Jan. 15, 2010 Press Release.) Thus, it is plain that the Board did not sit idly by while McNeil failed to correct known problems.

c. The 2009 and 2010 Fort Washington Recalls

Plaintiffs also allege that the Board faces a substantial likelihood of liability with respect to the recalls from McNeil's Fort Washington facility. Specifically, plaintiffs allege two distinct quality issues and resulting recalls at McNeil's Fort Washington plant: (1) the September 2009 recall of various children's medicines;

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and January 15, 2010, Warning Letter. Regardless, the Complaint contains no allegation, particularized or otherwise, of J&J Board knowledge of any such report.

and (2) problems resulting in the April 2010 recalls. There is no substantial likelihood of Board liability for either issue.

The only red flags alleged for either issue are the September 2009 and April 2010 recalls themselves. (*See* Cmplt. ¶¶ 282–85.) But again, because there is no allegation that the J&J Board knew of the problems underlying either recall before the recalls occurred, the J&J Board could not have done anything to prevent either recall.[8]

Moreover, McNeil has responded to the manufacturing concerns. As plaintiffs themselves plead, J&J made significant leadership changes in response to the recalls. (Cmplt. ¶ 124.) And the recalls themselves were a voluntary response to the Fort Washington plant's manufacturing problems. (*See, e.g.*, Sept. 30, 2010 Testimony of W. Weldon at 1-3.) Even before the April 2010 recalls and FDA inspection, McNeil had suspended production at Fort Washington and hired an expert consultant to help it remediate the plant's problems. (*Id.*) On May 25,

[8] The allegations attributed to confidential witnesses are irrelevant because they do not allege any J&J Board knowledge of any problems at McNeil's Fort Washington plant. (*See* Cmplt. ¶¶ 91, 153–55.) Moreover, the Court should consider the "detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Inst. Inv. Group v. Avaya, Inc.*, 564 F.3d 242, 263 (3d Cir. 2009). Where, as here, the confidential witnesses do not meet these criteria, then the Court "must discount them steeply." *Id.*

2010, McNeil announced the outlines of its remediation plan, and in July 2010 it submitted a Comprehensive Action Plan to the FDA addressing its manufacturing issues. (*Id.*; Cmplt. ¶ 285.) Given these undisputed remedial steps, plaintiffs cannot rely on unsupported, conclusory allegations that the J&J Board egregiously failed to see that McNeil took good faith measures to fix Fort Washington's problems.

d. The 2010 Vision Care and DePuy Recalls

Plaintiffs also seek to assert claims regarding recalls in late 2010 by J&J subsidiaries Vision Care and DePuy. (Cmplt. ¶¶ 126-34.) As a threshold matter, these events may not be used to establish demand futility because they occurred after plaintiffs commenced their suit. *See supra*, at 17 n.3.

Moreover, the Complaint does not allege that the Board knew of Vision Care's recall of Acuvue contacts or the underlying cause, let alone that the Board had knowledge at a time when it could have acted to prevent the issues leading to the recall. Nor do plaintiffs allege any violation of any country's regulations or laws, or that Vision Care did not follow proper procedures in any country affected by the recall.

Similarly, with respect to DePuy's recall of certain orthopaedic devices, plaintiffs do not provide particularized facts demonstrating that the Board knew of defects prior to the recall. Plaintiffs cite to a Warning Letter dated August 19,

2010, but the letter was not addressed to the Board and does not establish any wrongdoing by DePuy. Plaintiffs' allegations do not come close to excusing demand.

* * *

The Complaint also is sprinkled with allegations of unrelated recalls that occurred between 2004 and 2007. Plaintiffs appear to contend that these miscellaneous recalls were red flags that should have alerted the Board to the problems that led to the 2009 and 2010 recalls discussed above. (Cmplt. ¶¶ 86–90, 281-82.) But plaintiffs do not make any allegations that the causes of the 2004-2007 recalls were not promptly addressed by the Company. *Cf. Bronstein*, 2008 WL 4735230, at *5 (allegations that a company failed to respond to FDA warning letters must be supported by particularized facts). Moreover, plaintiffs do not plead any particularized facts explaining why the J&J Board should have thought that these miscellaneous recalls of unrelated products were not being addressed, particularly when recalls are inherent in the heavily-regulated healthcare industry.

2. The Off-Label Marketing Allegations Do Not Show That The Board Knowingly Acted Against The Interests Of The Company Or Knowingly Violated The Law.

Plaintiffs next allege that the Board consciously disregarded that certain J&J subsidiaries were allegedly improperly marketing their drugs (Risperdal, Topamax, and Natrecor) or products (biliary stents) for off-label uses, and thus claim that the

directors face substantial personal liability that excuses demand. (Cmplt. ¶¶ 164-253.) Plaintiffs claim that there were red flags that supposedly put the Board on notice of these practices. For example, plaintiffs note that the directors signed certain of the Company's public filings with the Securities and Exchange Commission, which listed the Company's ongoing litigation matters and disclosed subpoenas that had been received in connection with the Off-Label Marketing Allegations. Plaintiffs also point to three letters from the FDA, two issued five years apart in connection with Risperdal (dated January 5, 1999 and April 19, 2004), and one issued in connection with Topamax (dated September 15, 2004). (*Id.* ¶¶ 173, 181, 203.) Additionally, plaintiffs point to allegations made by confidential witnesses as to what J&J's management (not the Board) allegedly knew. (*Id.* ¶¶ 179-80, 201.) Plaintiffs then ask the Court to infer that the Board knew that off-label marketing was in fact taking place and intentionally allowed it to continue. Plaintiffs' allegations are plainly insufficient to excuse demand.

Analogous allegations were held to be insufficient in *In re Merck & Co., Inc. Securities, Derivative, and ERISA Litigation*, 2008 WL 2788400 (D.N.J. June 17, 2008). In that case, the derivative plaintiffs claimed, *inter alia*, that demand should be excused as futile because the Merck directors allegedly faced a substantial likelihood of liability for authorizing, approving, or consciously failing to prevent Merck from marketing its blockbuster drug Vioxx despite alleged warnings that

Vioxx had adverse risks. *Id.* at *3-4. The plaintiffs alleged that the board received and reviewed studies regarding Vioxx's safety profile and that the Chairman of Merck's board received a Warning Letter from the FDA reprimanding Merck for misrepresenting the safety of Vioxx when promoting the drug. *Id.* at *3. The plaintiffs claimed that, despite this purported knowledge regarding the risks of Vioxx, the board "nevertheless continued to sell and promote Vioxx" and "approved aggressive marketing campaigns" because the board was motivated by the drug's commercial success. *Id.*

Judge Chesler dismissed the complaint, holding that these allegations did not show that the directors faced a substantial likelihood of liability and that the plaintiffs were not excused from making a demand. *Id.* at *6. The complaint failed to "plead particularized facts regarding the [d]irectors' participation in the alleged wrongdoing, that is, exactly how they were involved in the failure to halt or decrease the promotion and sale of Vioxx." *Id.* at *7. "The inference [the] [p]laintiffs believe[d] should be drawn [was] that the Merck Board acted in bad faith by continuing to market a drug they knew was dangerous, all the while rejecting advice to conduct safety studies." *Id.* at *8. But the complaint did "not support [that] inference because it fail[ed] to connect allegations that Merck employees ignored known safety risks to its conclusions that Merck Directors did also." *Id.* Because "[a]n outside director is typically not involved in the day-to-

day operations of a business," allegations that the Board "'approved' and/or 'authorized' marketing strategies . . . without specific averments about individual [d]irectors' direct involvement in the challenged wrongdoing, do not cast doubt on the [d]irectors' disinterestedness." *Id.* at *7.[9]

The District of Delaware reached the same conclusion in *King v. Baldino*, 648 F. Supp. 2d 609 (D. Del. 2009), which the Third Circuit recently affirmed in *King v. Baldino*, 2010 WL 5078008 (3d Cir. Dec. 14, 2010). In *King*, the plaintiff alleged that the directors of Cephalon, Inc. breached their fiduciary duties by allowing the company to market three of its most successful pharmaceutical drugs for off-label uses. The plaintiff alleged that demand should be excused as futile because the directors faced a substantial likelihood of liability. According to the complaint, the directors allowed off-label marketing of the drugs for more than a six-year period, despite the fact the Board received warnings of the improper conduct, including the fact that several federal and state regulators had commenced investigations into the company's marketing practices. 648 F. Supp. 2d at 614, 621-26. The district court held that such allegations did not excuse demand because the plaintiff failed to plead particularized facts showing that the directors

[9] Moreover, plaintiffs may not "attribute illegal conduct" in blanket fashion to the entire board; they must make particularized allegations about each director's alleged wrongdoing. *Livermore v. Engles*, 2011 WL 291334, at *3 (N.D. Tex. Jan. 26, 2011) (dismissing derivative complaint).

knowingly allowed illegal marketing to continue. *Id.* at 623. To the contrary, Cephalon's public disclosures regarding the investigations stated that the Company was cooperating with the government and providing the requested documents. *Id.* at 625-26. The court thus dismissed the complaint.

The Third Circuit affirmed, emphasizing that the plaintiff failed to allege any red flags showing that the Board, as opposed to management, knew of the alleged problems. "The purported red flags that [the plaintiff] cite[d] all involve[d] the *company's* marketing and sales practices." 2010 WL 5078008, at *2 (emphasis in original). The plaintiff did "not allege any specific connection between any of those practices and the *board*." *Id.* (emphasis in original). The Third Circuit went on to state that the plaintiff "fail[ed] to realize that the directors' good faith exercise of oversight responsibility may not prevent employees from violating the laws, or from causing the corporation to incur significant financial liability, or both." *Id.* at *3 (quoting *Stone*, 911 A.2d at 373). Without particularized facts that the directors knew about the misconduct and consciously failed to act, the plaintiff could not establish that the defendants faced a substantial likelihood of personal liability. *Id.*

Just as in *Merck* and *King*, plaintiffs' allegations here do not excuse demand.

a. The Risperdal and Topamax Allegations

With respect to Risperdal and Topamax, plaintiffs point to the following purported red flags: (1) letters received from the FDA (Cmplt. ¶¶ 173, 181, 203); (2) certain *qui tam* litigation and government investigations (*id.* ¶¶ 169-70, 196, 207); and (3) statements by confidential witnesses regarding promotional materials for the drugs (*id.* ¶¶ 179, 201). None of these allegations excuses demand.

As a threshold matter, plaintiffs mischaracterize the letters received from the FDA. Two of the letters (dated April 19, 2004 and September 15, 2004, attached as Exs. 4 and 5 to Robinson Cert.) reflected the FDA's concerns that certain specific promotional materials and communications with healthcare professionals needed to be modified – the letters did not claim that the subsidiaries were improperly promoting their drugs for off-label uses.[10] The third letter (dated January 5, 1999, attached as Ex. 6 to Robinson Cert.) is not even a Warning Letter.[11]

Moreover, the Complaint contains no allegations that J&J's outside directors ever received or discussed those letters, which were sent to the subsidiary

[10] The Court can consider the letters because they are integral to plaintiffs' complaint and explicitly relied upon therein. *Merck*, 2008 WL 2788400, at *4.

[11] The January 5, 1999 letter is an "untitled letter," which is informal correspondence from the FDA regarding matters that do not rise to the level of a Warning Letter. *See* FDA Regulatory Procedures Manual, Ch. 4, Advisory Actions 4-2 (2010) (available at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf).

companies. *See Merck*, 2008 WL 2788400, at *3-4; *Intel*, 621 F. Supp. 2d at 169-76; *see also Bronstein*, 2008 WL 4735230, at *4-5 (dismissing derivative action where directors received FDA warning letter but plaintiffs did not plead particular facts showing what the Board did with the letter or how it responded). Although the two letters in 2004 were copied to Mr. Weldon, plaintiffs make no allegations that the letters were ever shared with the Board, let alone that the Board determined there had been misconduct and intentionally allowed it to continue. Plaintiffs may not impute knowledge to the Board; it must be particularly pleaded. *See, e.g.*, *Merck*, 2008 WL 2788400, at *3-4. All plaintiffs do is make "conclusory allegation[s] that because illegal behavior [allegedly] occurred . . . the board must have known so," and such allegations are grossly insufficient. *Medtronic*, 622 F. Supp. 2d at 812; *see also King*, 2010 WL 5078008, at *3.[12]

Nor does the receipt of subpoenas in connection with governmental investigations or the filing of litigation demonstrate that the Board faces a substantial likelihood of liability. First, the subpoenas were received and the litigation was filed *after* the allegedly improper marketing practices had already occurred. The Topamax Allegations appear to claim that Ortho-McNeil

[12] Moreover, plaintiffs have made no particularized allegations that either the subsidiaries or Mr. Weldon failed to respond to the letters. There is thus no basis to infer that the subsidiaries did not appropriately respond to the FDA and take prompt action to address the FDA's concerns.

improperly marketed the drug from 2001-2003. (*See* Cmplt. ¶ 196 (citing *qui tam* complaints alleging that time period).) The first subpoena was not received until December 2003 and the *qui tam* action was not unsealed until 2006. (Cmplt. ¶¶ 206-207.) And the Risperdal Allegations refer to a government investigation of Janssen's marketing practices from 1997-2002 and litigation regarding marketing practices in 2003 and early 2004. But the first subpoena relating to Risperdal was received in 2004: it thus could not have been a red flag.[13]

Second, the Complaint makes no allegations as to whether and with whom the Board discussed the subpoenas, what information was presented to the Board, or what decisions the Board reached regarding the appropriateness of the conduct at issue. Moreover, just as in *King*, J&J's public filings make clear that the Company cooperated with each investigation and responded to the subpoenas. (*See, e.g.*, J&J Form 10-Q, filed August 10, 2005, at 27-28.) Plaintiffs' mere cataloguing of J&J's public disclosures regarding the ongoing investigations does

[13] As for time periods after 2004, plaintiffs state that a complaint filed by the Louisiana Attorney General alleged that off-label promotion occurred through 2008 and that the action resulted in a jury award on October 15, 2010 against the Company. (Cmplt. ¶ 191.) But plaintiffs mischaracterize the record. The jury found only that during 2003 and 2004 the safety of Risperdal had been misstated in violation of Louisiana's Medical Assistance Program Integrity Law. (*See¸ e.g.*, Plaintiffs' Motion in Limine, at 1, filed July 19, 2010, in *Louisiana v. Janssen Pharma., Inc. et. al.*, Case No. 04-C-3967, attached as Ex. 7 to Robinson Cert.) It did not make any findings of wrongdoing with respect to conduct after 2004. Accordingly, none of the subpoenas or litigation discussed by plaintiffs constitute red flags that were ignored as evidenced by subsequent misconduct.

not constitute a particularized allegation that the Board knew J&J's subsidiaries were engaged in illegal conduct and did nothing to stop it. *See Intel*, 621 F. Supp. 2d at 175; *King*, 648 F. Supp. 2d at 623-24.

Nor do the allegations attributed to confidential witnesses establish that demand on the Board would be futile. With respect to Risperdal, CW1, allegedly a Region Business Director, claims that there was a clear direction to sell Risperdal to elderly patients for treatment of dementia and Alzheimer's diseases, both unapproved uses of the drug. (Cmplt. ¶ 179.) CW1 does not state, however, that the Board was ever made aware of that "clear direction," let alone endorsed it. CW1 also alleges that CEO Weldon was aware of the amount of Risperdal sales for off-label uses. (*Id.* ¶ 180.) However, as discussed above, the fact that Risperdal was prescribed by physicians off-label is neither unusual nor illegal. Thus, the fact that Mr. Weldon was allegedly aware that Risperdal's sales included off-label uses says nothing about Janssen's compliance with FDA marketing regulations. Moreover, CW1 says nothing about what J&J's *outside directors* knew.

With respect to Topamax, the Complaint claims that CW2 was a sales representative who can "confirm" that J&J's subsidiary, Ortho-McNeil, used "key opinion leaders and medical conferences to market Topamax for off-label uses."

(*Id.* ¶ 201.) Significantly, as with CW1, CW2 says nothing about what senior J&J management knew, let alone what the J&J Board knew.

b. The Natrecor Allegations

Plaintiffs point to only one purported red flag regarding Natrecor. They claim that because J&J conducted due diligence and the Board in 2003 approved the acquisition of Scios (the subsidiary that manufactured and marketed Natrecor), the Board at that time must have known that Scios would illegally market Natrecor for off-label uses. (*Id.* ¶ 226.) That is nonsense. There are absolutely no allegations that J&J's directors learned during the due diligence process that Scios improperly marketed Natrecor or that Scios would do so after the acquisition. All plaintiffs point to is the fact that Natrecor sales (both on- and off-label) increased after the acquisition (*id.* ¶¶ 229-30), but again, there is nothing illegal or improper about off-label sales.

c. The Biliary Stent Allegations

Plaintiffs allege that J&J subsidiary Cordis improperly marketed biliary stents from 1996-2007. They point to two events that supposedly alerted the Board to Cordis's alleged off-label marketing of biliary stents and excuse demand: (1) a *qui tam* complaint filed on September 26, 2006 (*id.* ¶ 246); and (2) a subpoena for documents received from the U.S. Attorney's Office for the District of Massachusetts in June 2008 (*id.* ¶ 251).

Plaintiffs are wrong. The *qui tam* complaint was filed under seal on September 26, 2006, and was not known to J&J at that time. (*See U.S. v. Abbott Labs., Inc. et. al.*, Case No. 06-1769, Dkt. No. 1.) The U.S. government, after a multi-year investigation, declined to intervene in December 2009. (*Id.* at Dkt. No. 53.) Similarly, the subpoena was not received until a year after the alleged misconduct is alleged to have stopped. (*See* J&J Form 10-Q, filed August 4, 2008.) Plaintiffs' allegations fail to show that the Board cannot fairly consider a demand.

3. The Omnicare And DePuy Allegations Do Not Show That The Board Knowingly Acted Against The Interests Of The Company Or Knowingly Violated The Law.

Plaintiffs' allegations with respect to Omnicare and DePuy are equally insufficient to excuse demand.

a. The Omnicare Allegations

As for Omnicare, plaintiffs allege that from 1999–2004, Janssen and JJHCS paid kickbacks to Omnicare in exchange for Omnicare's pharmacists recommending certain Janssen drugs to nursing home patients. (Cmplt. ¶¶ 255-72.) But plaintiffs do not point to any red flags that supposedly put the Board on notice of this alleged practice. At most, plaintiffs point to a settlement between the government and Omnicare in 2009 (*id.* ¶ 270) and the government's intervention in a *qui tam* complaint against J&J in 2010 (*id.* ¶ 271). Both of these actions

occurred *years* after the conduct at the two subsidiaries is alleged to have stopped. Plaintiffs have not made any particularized allegations showing that the Board knew about any improper behavior regarding Omnicare but did nothing to stop it.

b. The DePuy Allegations

As for DePuy, plaintiffs allege that from 2002–2006, DePuy Orthopaedics paid inducements to surgeons to use DePuy hip and knee replacement and reconstructive products in their surgeries. (*Id.* ¶¶ 273-77.) Plaintiffs claim that the Board faces a substantial likelihood of liability with respect to these allegations because subsidiary DePuy (not J&J) received a subpoena in March 2005 seeking records concerning contractual relationships between DePuy and surgeons involved in hip and knee replacement and reconstructive surgery.

But as J&J's quarterly filing with the SEC, dated May 10, 2005, explained, orthopaedic companies generally were the subject of the investigation, not just J&J. (*See* J&J Form 10-Q, at 24, filed May 10, 2005.) The filing stated that "[o]ther leading orthopaedic companies are known to have received the same subpoena" and that DePuy was cooperating with the investigation. (*Id.*) Plaintiffs make no particularized allegations that the J&J Board knew of any wrongdoing at DePuy and consciously disregarded it. Indeed, when DePuy entered into its settlement agreement with the United States in 2007 regarding this investigation, DePuy specifically "denie[d] that it engaged in any wrongdoing" and the

settlement was accepted as "neither an admission of any facts or liability by DePuy." (*See* DePuy Settlement Agreement, attached as Ex. 8 to Robinson Cert.)

D. The Existence Of Litigation, Regulatory Investigations, And Recalls Does Not Establish A Substantial Likelihood Of Liability.

Because they cannot point to any individual red flags that the Board ignored, plaintiffs conclusorily allege instead that the Board faces a substantial likelihood of liability because the number of suits, regulatory investigations, and product recalls since 1997 shows that the directors "must have known" of systemic problems at the Company and yet intentionally failed to correct them. (*See, e.g.*, Cmplt. ¶¶ 3, 286-90.) Plaintiffs' conclusory allegation is not supported by the facts or the law.

The context here is critical. J&J is an extremely large, complex, and successful company. It has more than 250 subsidiaries operating all around the globe. Those subsidiaries operate in the closely-regulated healthcare industry, with its ever-changing regulatory environment, in which companies like J&J routinely interact with federal agencies, respond to government inquiries, issue recalls, and defend litigation.

That a handful of J&J's 250 subsidiaries have been the subject of regulatory action or litigation at various times over the past fourteen years in no way suggests that the Board was not exercising its responsibilities. Likewise, that J&J has had product recalls by a few subsidiaries does not show a systemic problem, nor does it

suggest that the Board knowingly encouraged the subsidiaries to disregard manufacturing regulations.

The recent decision in *Medtronic Derivative Litigation*, 622 F. Supp. 2d 802 (D. Minn. 2009), is directly on point. The plaintiff in that case alleged that the directors were on "heightened notice" of issues concerning a recalled product and the alleged off-label marketing of one of the company's leading pharmaceutical drugs "because of prior litigation and enormous payouts arising from similar defects and issues." *Id.* at 812. The plaintiff contended that Medtronic had a "long history of improper promotion" of various products and that it had settled prior litigation for $40 million. *Id.* The plaintiff also alleged that the company had a history of recalls and settled one lawsuit related to a prior recall for $114 million. *Id.* The court dismissed the complaint, holding that the plaintiff did not plead particularized facts showing that the challenged settlements of prior litigation were anything other than "routine business decisions in the interest of the corporation"; none of the directors was a defendant in any of the *qui tam* lawsuits referenced in the complaint; and the plaintiff did not plead particularized facts showing what the Board actually knew and allegedly disregarded. *Id.*[14]

[14] The court also held that, to the extent the plaintiff alleged that the prior lawsuits put the directors on notice that they should be paying closer attention to a particular product line, that allegation was at most a breach of the duty of care,

Also on point is *In re Intel Corp. Derivative Litigation*, 621 F. Supp. 2d 165 (D. Del. 2009), which likewise rejected the argument plaintiffs make here. In that case, Intel was the subject of multiple investigations by various government agencies, one of which resulted in a $25 million fine. *Id.* at 169. Just as here, the plaintiff pointed to the company's SEC filings, which were signed by nine of the defendant directors and which publicly reported the ongoing investigations. *Id.* at 174. The plaintiff alleged that "these investigations constitute[d] 'red flags signaling persistent corporate malfeasance' that the [directors] ha[d] ignored in violation of their fiduciary duty of loyalty." *Id.* at 169.

The *Intel* court rejected the plaintiff's argument. Although there had been a number of investigations, the plaintiff failed to identify what the directors actually knew about such alleged red flags or how they responded to them. "Simply put, when it comes to 'red flags,' [the] [p]laintiff's approach [was] little more than to catalog the ongoing investigations into Intel's alleged wrongdoing, and then assert that the thickness of the catalog demonstrates that Intel's conduct was so egregious and widespread that the [d]irectors certainly must now face at least a 'substantial

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which was an exculpated claim and did not excuse demand. 622 F. Supp. at 812. *See supra*, at 20-21.

likelihood' of personal liability for having ignored the 'red flags.'" *Id.* at 175. The court held that such allegations did not excuse demand. *Id.*[15]

That is precisely the case here. Plaintiffs simply list instances of alleged misconduct without providing particularized facts regarding the Board's knowledge of, or responses to, any of them. J&J has properly defended the actions brought against it and has responded to, and sought to rectify, every regulatory or manufacturing problem of which it has become aware. Plaintiffs have not alleged a basis for concluding that the settlements to which J&J agreed were "anything other than routine business decisions in the interest of the corporation." *See Medtronic*, 622 F. Supp. 2d at 812. In these circumstances, plaintiffs' allegations fall far short of showing that the Board knew of systemic problems at J&J and intentionally allowed them to continue.[16]

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[15] The New Jersey Supreme Court also has rejected the argument that the existence of regulatory investigations establishes that the directors face a substantial likelihood of liability. In the *PSE&G* case, the plaintiffs alleged that equipment failures at various times at several nuclear facilities, combined with regulatory scrutiny from the United States Nuclear Regulatory Commission and fines, demonstrated a pervasive failure of the PSE&G board to oversee the company's nuclear plants. 173 N.J. at 268-70. The plaintiffs sent the board of directors a letter demanding that the board take certain action, which, after an investigation, the board declined to pursue. The court upheld the board's determination, holding that the board was independent and disinterested and could properly consider a shareholder demand. *Id.* at 289-91. In doing so, it did not find that the regulatory scrutiny rendered the board interested.

[16] This case is very different from the allegations found sufficient to excuse demand in *In re Pfizer, Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d

E. The Directors' Service On Board Committees Does Not Establish A Substantial Likelihood Of Liability.

Plaintiffs' final basis to excuse demand is their claim that nine of the directors allegedly face a substantial likelihood of liability because they allegedly knew of the purported misconduct through their service on the Board's Audit Committee, Public Policy Advisory Committee, and/or Science and Technology Advisory Committee, and yet "declin[ed] to stop and prevent" it. (Cmplt. ¶¶ 298-300, 306.) Plaintiffs imply that service on these committees necessarily means that the directors knew of the alleged misconduct at J&J's subsidiaries. (*Id.*) Plaintiffs do not, however, point to *any* particular information that the directors supposedly learned during committee meetings, let alone any specific facts showing that any director intentionally decided to allow wrongdoing to continue.

Conclusory allegations of precisely this type have been consistently rejected as insufficient to excuse demand under New Jersey and Delaware law.[17] *See, e.g.*,

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453 (S.D.N.Y. 2010). In that action, the plaintiffs alleged that the Pfizer board knowingly condoned off-label marketing of at least fifteen different drugs, including seven of Pfizer's nine most profitable drugs, over a period of eight years. During that period, the Pfizer board was itself subject to two Corporate Integrity Agreements, which were the result of prior settlements related to yet other off-label marketing litigation. In the Corporate Integrity Agreements, Pfizer specifically had agreed that any information that management possessed regarding off-label drug promotion would be communicated to the board. Plaintiffs here do not allege any similar facts or conduct.

[17] New Jersey applies the same standard for demand futility as Delaware. *PSE&G*, 173 N.J. at 282; *Kanter*, 388 F. Supp. 2d at 478.

Richardson, 2007 WL 2713050, at *14 (dismissing for failure to make a demand: "[l]isting the responsibilities of . . . [the company's] audit committee members does not raise a reasonable doubt as to whether these persons were aware that [the company] was disseminating false or misleading information"); *Fagin v. Gilmartin*, 2004 WL 5835749, at *8 (D.N.J. Aug. 20, 2004) (dismissing for failure to make a demand: although complaint described duties and obligations of audit committee defendants, it was "devoid of any particularized facts" challenging presumption that board acted with independence and disinterest); *Jannett v. Gilmartin*, 2006 WL 2195819, at *5-6 (N.J. Super. Ct. L. Div. July 21, 2006) (dismissing for failure to make a demand: allegations that directors served on Compensation and Benefits Committee insufficient to excuse demand).

Here also, the decision in *Medtronic* is instructive. The plaintiff alleged that the Medtronic directors on the Audit Committee and the Technology and Quality Committees must have had knowledge of the need for a product withdrawal because "the 'charters designating the responsibilities of [those] committees created corporate governance structures designed to prevent exactly the type of wrongdoing complained of' in the Complaint." 622 F. Supp. 2d at 811. The court rejected such conclusory allegations and dismissed the complaint for failure to make a demand, holding that "it is well settled that committee membership is an insufficient basis on which to infer knowledge." *Id.*

Similarly, in *Bronstein v. Austin*, 2008 WL 4735230 (N.D. Ill. May 30, 2008), the court dismissed a derivative complaint that alleged that the Board of Directors of Abbott Laboratories knowingly ignored compliance violations at its manufacturing facilities. The complaint alleged that the directors on the Public Policy Committee must have known about the non-compliance issues because the Committee's charter included procedures to "ensure that the [d]irectors would receive all of the information from management concerning FDA regulatory compliance issues." *Id.* at *4. The court held that such allegations "fall[] short of pleading particularized facts establishing bad faith on the part of the [d]irectors." *Id.* at *5. The plaintiff did not make any particularized allegations that by virtue of their Committee membership, any of the directors actually learned of the alleged misconduct and failed to take corrective action. *Id.*

Just as in those cases, plaintiffs' conclusory allegation that the J&J directors must have known of alleged misconduct at J&J subsidiaries by serving on Board committees does not establish demand futility. Plaintiffs make no particularized allegations regarding what documents or reports were received in those committee meetings. Nor do plaintiffs make particularized allegations regarding what kind of alleged illegal conduct the committee members learned and discussed, let alone intentionally ignored. Plaintiffs' allegations based on committee membership are wholly unavailing.

* * *

In sum, plaintiffs have failed to plead particularized facts showing that this is one of the rare cases where the directors' conduct was so egregious (*i.e.*, that the directors knowingly acted against the best interests of the Company or knowingly violated the law) that they face a substantial likelihood of liability that excuses demand. Accordingly, the Complaint should be dismissed.

II. IN THE ALTERNATIVE, THE COURT SHOULD STAY THIS ACTION PENDING THE SPECIAL COMMITTEE'S INVESTIGATION.

Although plaintiffs in this case did not do so, nine other J&J shareholders have made demands upon the J&J Board that it investigate and evaluate whether any claims should be brought. Those demands encompass essentially all of the matters set forth in plaintiffs' Complaint. (*See* Decl. of D. Eakeley ¶¶ 3-5.)

Consistent with New Jersey law, upon receiving those demands, the J&J Board appointed a Special Committee to investigate the allegations made in those demands and to recommend to the Board what actions, if any, should be taken. (*See id*.) In addition, the Special Committee has been given the same authority and responsibility with respect to the allegations in this derivative suit. The Special Committee is comprised of four independent directors. It is doing precisely what New Jersey law asks it to do: it is actively investigating the demands of the shareholders with the assistance of independent outside counsel. (*See id.* ¶ 6.) The

J&J Board has acted promptly and responsibly. The Special Committee should be allowed to complete its task so that the Board is afforded a reasonable opportunity to decide whether any of these claims are in the best interests of J&J.

As discussed *supra* at 14, one of the fundamental powers of J&J's Board is the "decision to bring a lawsuit or to refrain from litigating a claim on behalf of the corporation." *Merck*, 493 F.3d at 399; *see also PSE&G*, 173 N.J. at 282. "If [that right] is to be meaningful, then . . . an independent committee, once appointed, should be afforded a reasonable time to carry out its function." *Abbey v. Computer & Commc'ns Tech. Corp.*, 457 A.2d 368, 372-75 (Del. Ch. 1983) (granting motion to stay because the right of the independent committee to investigate and report its findings must "take priority" over the pending action).

As a result, courts routinely stay derivative litigation to allow special committees to evaluate the claims made by a shareholder. *See, e.g.*, *In re InfoUSA, Inc. S'holders Litig.*, 2008 WL 762482, at *1-3 (Del. Ch. Mar. 17, 2008); *Rudolph v. Cummins*, 2007 WL 1189632, at *1-4 (S.D. Tex. April 19, 2007); *In re United Health Group Inc. S'holder Deriv. Litig.*, 2007 WL 803048, at *1-2 (D. Minn. Mar. 14, 2007); *St. Clair Shores Gen. Employees Ret. Sys. v. Eibeler*, 2006 WL 2849783, at *2-3 (S.D.N.Y. Oct. 4, 2006); *Strougo v. Padegs*, 986 F. Supp. 812, 814–16 (S.D.N.Y. 1997). Indeed, given the importance of the Board's right to

control corporate litigation, the general rule is that the "propriety of a stay is presumed." *St. Clair Shores*, 2006 WL 2849783, at *3.

The J&J Board should have an opportunity in the first instance to investigate and respond to the various allegations. Accordingly, in the alternative, the Court should stay this action pending the Special Committee's investigation.

CONCLUSION

For the foregoing reasons, nominal defendant J&J respectfully requests that the Court dismiss the Consolidated Amended Complaint, or, in the alternative, stay this action pending the completion of the Special Committee's investigation.

Respectfully submitted,

s/ Donald A. Robinson

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